

**UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF NEW YORK**

**BRECKENRIDGE PHARMACEUTICAL,
INC,**

Civil Action No.: 07-CV-11114(RWS)

Plaintiff,

vs.

MIDLAND HEALTHCARE, LLC.

Defendant.

**RULE 56.1 (b) DECLARATION OF COUNTER-STATEMENT OF FACTS IN
OPPOSITION TO THE MOTION FOR SUMMARY JUDGMENT**

In opposition to the instant motion for summary judgment, Defendant Midland Healthcare, LLC, ("Midland") submits the following response to Plaintiff's Statement of Undisputed Facts, and alleges the following facts raise genuine issues of fact to be tried:

1. The Plaintiff ("Breckenridge") and Defendant ("Midland") entered into an ANDA Development, Manufacture and Supply Agreement ("Agreement"), sections of which are annexed to as Exhibit "B" to the Memorandum of Law submitted herewith and referred to by the declaration of Raman Kapur also submitted in opposition to Plaintiff's motion.
2. Defendant had developed pilot formulation and Plaintiff had been informed prior to execution of the Agreement that initial development work would be conducted in India and be supplemented by work in the U.S. Kapur Decl., ¶ 3
3. The subject formulation had been developed prior to the Agreement and plaintiff had been informed that a stability study had been conducted in India and that the study was to be repeated with the batch of the product that would be used to

make the submission for the Abbreviated New Drug Application (ANDA) for the U.S. F.D.A Kapur Decl., ¶4

4. Contrary to the assertions in Mr. Lapila's declaration Midland has performed a considerable amount of the work required as per the Agreement as follows:

PHASE I: Preformulation.

1. Assay Method for Drug Product development purpose
2. API Sourcing and acquisition:
 - Audit of supplier of active materials in India
 - Review of Drug Master File (DMF) and forwarding

DMF Documentation to Breckenridge

PHASE II: Formulation Development (R&D) and Dissolution Testing

1. Miscellaneous equipment change parts needed for Liquid Line were procured
2. Supplementary formulation development work was conducted at Midland
3. Development of initial test methods for pilot studies in the U.S.
4. Packaging procurement and R&D Packaging for machine check

PHASE III: Process Development

1. Non GMP prototype batch (3) production
2. Product development testing
3. Establishment of IPC tests, etc.

PHASE IV: Analytical Method Development and Validation

1. Stability indicating method development for assay and impurities
2. Validation of methods using final formulation developed in PHASE III
3. Analytical method development report

PHASE V: Pilot GMP Batch

1. Establishment of IPC and Finished Product Controls beyond PHASE III
2. Preparation of batch records for non GMP batch
3. Raw materials testing and release
4. Production of prototype on GMP batch
5. In Process Testing of Prototype non GMP batch for standard tests
6. Packaging (pilot GMP batch)
7. Final release testing of non GMP with Certificate of Analysis
8. Cleaning Verification (methods, validation, testing, etc.)
9. Innovator reference samples and testing

Development Report

5. In accordance with the Agreement, Midland carried out the development work and had regular conferences with Breckenridge concerning progress of the product. Kapur Decl., ¶6
6. Plaintiff's assertions that an email sent by Mr. Lapila wherein he asserted that the project "died due to Midland's failure to get it up on stability in a timely manner", and Midland's reply to the email are evidence that Defendant somehow "effectively admits them" are unfounded. (See Plaintiff Rule 56.1 Statement ¶s 18 and 19). As a matter of fact, a trial on the issues of this matter will reveal that Plaintiff had learned that the product at issue had been switched by the Food and Drug Administration from an Rx (Prescription) status to a Over the Counter (OTC) status greatly reducing the value of the product and was looking for any opportunity to exit the project. Kapur Decl., ¶s 7 and 8
7. Plaintiff did not terminate this project in accordance with the explicit terms of the Agreement and never allowed Midland an opportunity to "cure" any alleged breaches within the 60 day time period provided for in the Agreement¹.

¹See Exhibit A attached to the Memorandum of Law, particularly ¶7.2 (b)

8. Substantial monies have been spent by Midland in furtherance of the project and, subject to the terms of the Agreement, are to be calculated in arriving at any sums either due from, or owing to Breckenridge. (Section 7.2 (b) of the Agreement).

New York, New York

February 26, 2008

/s/ Bruce Regenstreich

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